OCT 1 7 2002 Applicant:

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Philippa RADCLIFFE et al.

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Title:

TRANSGENIC ORGANISM

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Appl. No.:

FECH CENTER 1600 2900

Filing

02/26/2002

10/082,122

Date:

Examiner:

Unassigned

Art Unit:

1632

#### INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.56

Commissioner for Patents Washington, D.C. 20231

Sir:

Submitted herewith on Form PTO-1449 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a prima facie art reference against the claims of the present application.



#### TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits, and within three (3) months of the mailing date of the foreign search report.

#### RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-1449 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date (+ 1) 1662

**FOLEY & LARDNER** 

Customer Number: 22428

Facsimile:

Telephone: (202) 672-5538 (202) 672-5399

Attorney for Applicant

Registration No. 34,717

Michele M. Simkin

By //) . L. - (, , , , / / , 6,

Page 1 of 1 SERIAL NO. Form PTO-1449 U.S. DEPARTMENT OF COMMERCE ATTY, DOCKET NO. (MODIFIED) PATENT AND TRADEMARK OFFICE 078883-0145 10/082,122 APPLICANT INFORMATION DISCLOSURE CITATION Philippa RADCLIFFE et al. **GROUP ART UNIT** FILING DATE 1 7 2002 1632 (Use several sheets if necessary) 02/26/2002 **U.S. PATENT DOCUMENTS FILING DATE DOCUMENT** SUB-**CLASS** DATE NAME **REF CLASS** INITIAL NUMBER **APPROPRIATE** RECEIVED DCT 1 8 2007 TECH CENTER 1600-2900 **FOREIGN PATENT DOCUMENTS** TRANSLATION DOCUMENT SUB-DATE COUNTRY CLASS REF **CLASS** NUMBER YES NO **United Kingdom** GB 2334257 18.08.1999 **A1** GB 2228487 29.08.1990 United Kingdom A2 WO 00/66758 A1 09.11.2000 World **A3** OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) M.A. Curran et al. "Efficient Transduction of Nondividing Cells by Optimized Feline Immunodeficiency Virus Vectors", Molecular Therapy Vol. 1, No. 1, January 2000, pp. 31-38. Julie C. Johnston et al. "Minimum Requirements for Efficient Transduction of Dividing and Nondividing Cells by Feline Immunodeficiency Virus Vectors", Journal of Virology, Vol. 73, No. 6, June 1999, pp. 4991-5000. **DATE CONSIDERED EXAMINER** 10/14/04 EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include any copy of this form with next communication to applicant.



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Unassigned

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# TECH CENTER 1800/2800 **INFORMATION DISCLOSURE STATEMENT** UNDER 37 CFR §1.56

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Respectfully submitted,

Michele M. Simkin

Attorney for Applicants Registration No. 34,717

FOLEY & LARDNER

Customer Number: 22428

Date Holl 11, 7023

22428

PATENT TRADEMARK OFFICE

Telephone:

(202) 672-5538

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PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

078883-0145

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB P Complete if Known Substitute for form 1449B/PTO **Application Number** 10/082,122 INFORMATION DISCLOSURE 02/26/2002 STATEMENT BY APPLICANT Filing Date Philippa RADCLIFFE e First Named Inventor Date Submitted: April 11, 2003 Group Art Unit 1632 PRADENTA (use as many sheets as necessary) **Examiner Name** Unassigned

Attorney Docket Number

	U.S. PATENT DOCUMENTS											
Examiner Initials*	Cite —	U.S. Patent Number	Document  Kind  Code <sup>2</sup> (if  known)	··· Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear						
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	A2	wo	03/022040	A2	CALIFORNIA INSTITUTE OF TECHNOLOGY	03/20/2003		

		NON PATENT LITERATURE DOCUMENTS	
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90	A3	LOIS ET AL., "Germline Transmission and Tissue-Specific Expression of Transgenes Delivered by Lentiviral Vectors," <i>Science</i> (1 February 2002), Vol. 295, pp. 868-872.	:
1-:	A4	QIN ET AL., "Inhibiting HIV-1 infection in human T cells by lentiviral-mediated delivery of small interfering RNA against CCR5," <i>PNAS</i> (January 7, 2003), Vol. 100, No. 1, pp. 183-188.	:
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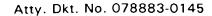
Date Considered 10/14/04

\*EXAMINER Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\* Unique citation designation number \*See attached Kinds of U.S. Patent Documents \*\* Enter Office that issued the document, by the two-letter code (WIPO Standard ST 3) \*For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the senal number of the patent document \*\* Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST 16 if possible \*\* Applicant is to place a check mark here if English Japanese Translation is attached.\*\*

Burden Hour Statement This form is estimated to take 2.0 hours to complete Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer. U.S. Patent and Trademark Office, Washington, D.C. 20231 DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS SEND TO Assistant Commissioner for Patents, Washington, D.C. 20231





#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Philippa RADCLIFFE et al.

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TRANSGENIC ORGANISM

Appl. No.:

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Filing Date:

02/26/2002

Examiner:

Unassigned

Art Unit:

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# UNDER 37 CFR § 1.56

Commissioner for Patents Washington, D.C. 20231

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#### TIMING OF THE DISCLOSURE

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#### **RELEVANCE OF EACH DOCUMENT**

Any document listed on the attached PTO/SB/08 was cited as being relevant during the prosecution of the corresponding United Kingdom application. A copy of the United Kingdom Search Report is attached setting forth the portion of each document considered relevant by the examiner.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

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Respectfully submitted,

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Attorney for Applicants Registration No. 34,717

FOLEY & LARDNER

Customer Number: 22428

JAN 1 6 2003

22420

PATENT TRADEMARK OFFICE

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Facsimile: (202) 672-5399

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449B/PTO
INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

Date Submitted: 01/16/2003

(use as many sheets as necessary)

Number

U.S. Patent Document

Kind

Code<sup>2</sup> (if known)

Sheet

Examiner

Initials\*

Cite

No.

	Complete if Known	7
Application Number	10/082,122	1
Filing Date	02/26/2002	1
First Named Inventor	Philippa RADCLIFFE	e/al
Group Art Unit	1632	1
Examiner Name	Unassigned	
Attorney Docket Number	078883-0145	

		U.S	. PAT	ENT	DOC	UME	NTS										
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		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	Τ <sup>6</sup>
70	A4	TARANTAL ET AL., "Lentiviral Vector Gene Transfer into Fetal Rhesus Monkeys ( <i>Macaca mulatta</i> ) <i>Mol. Ther.</i> (2001), Vol. 4, No. 6, pp. 614-621.	,
	A5	WOLFGANG ET AL., "Rhesus monkey placental transgene expression after lentiviral gene transfer into preimplantation embryos," <i>Proc. Natl. Acad. Sci. USA</i> (2001), Vol. 98, No. 19, pp. 10728-10732.	
	Ā6	STEIN ET AL., "In Vivo Treatment of Hemophilia A and Mucopolysaccharidosis Type VII Using Nonprimate Lentiviral Vectors," Mol. Ther. (2001), Vol. 3, pp. 850-856.	•
	A7 .	BERKOWITZ ET AL., "Construction and Molecular Analysis of Gene Transfer Systems Derived from Bovine Immunodeficiency Virus," <i>J. Virol.</i> (2001), Vol. 75, No. 7, pp. 3371-3382.	•
	A8	TARANTAL ET AL., "Rhesus Monkey Model for Fetal Gene Transfer: Studies with Retroviral-Based Vector Systems," <i>Mol. Ther.</i> (2001), Vol. 3, No. 2, pp. 128-138.	

Examiner Signature

Joe Worlan

Date Considered

10/14/04

\*EXAMINER Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Unique citation designation number "See attached Kinds of U.S. Patent Documents." Enter Office that issued the document, by the two-letter code (WIPO Standard ST 3). "For Japanese patent documents, the indication of the year of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. "Applicant is to place a check mark here if English language Translation is attached."

Burden Hour Statement. This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO. Assistant Commissioner for Patents, Washington, D.C. 20231.

674523-2024



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Radcliffe et al.

U.S. Serial No.

10/082,122

Filing Date

February 26, 2002

For

TRANSGENIC ORGANISM

Examiner

Unssigned

Art Unit

1632

745 Fifth Avenue New York, NY 10151

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on September 5, 2003.

Thomas J. Kowalski, Reg. No. 32,147

Name of Applicant, Assignee or Regis

September 5, 2003

Date of Signature

### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Further to the Information Disclosure Statements filed on October 17, 2002, November 25, 2002, January 16, 2003 and April 1 2003, the Examiner's attention is respectfully directed to the accompanying document listed on form PTO-1449.

To the extent that a petition is necessary for consideration of this Information Disclosure Statement, this paper will serve as such. Further, these documents were first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the statement.

It is respectfully requested that the Examiner considers and make of record the document cited herewith and that a copy of Form PTO-1449 be initialed by the Examiner and returned to the undersigned.

The filing of this Information Disclosure Statement is not an admission that the document identified herein constitutes prior art to the present application.

As this Information Disclosure Statement is being submitted before receipt of an Office Action, it is believed that no fee is due for the consideration of this document. If, however a fee is due, the Commissioner is authorized to charge any necessary Petition fee, or any additionally required fee, or credit any overpayment, to deposit account 50-0320.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

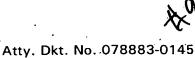
Attorney for Applicants

Thomas/J. Kowalsk

Reg. No. 32,147 (212) 588-0800

Encls. - PTO Form 1449 - 2 References

Based on Form	PTO-1449				ATTY. DOCKET NO.		SERIAL NO.		Sheet 1 01 )
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Art Unit:

Examiner:

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Michele M. Simkin Attorney for Applicant

Registration No. 34,717

July M Minlin

Date Nov 25, 2002

FOLEY & LARDNER

Customer Number: 22428

22428

PATENT TRADEMARK OFFICE

Telephone: Facsimile: (202) 672-5538

(202) 672-5399

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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	Substitute for fo	orm 1449B	/PTO		Complete if Known					
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	Date Submitted: N	lovember	25, 2002	Group Art Unit	1632	*				
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Sheet	1	of	5	Attorney Docket Number	078883-0145	TRADE				

					F	DREIGN PATENT DOCUMENTS			
Examine Initials*	Cite No.1	Foreign Patent Document  Office <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if knowin)			ode <sup>5</sup>	Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T 6
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	А3	wo	92/21766		A1	BOEHRINGER MANNHEIM GMBH et al.	12-10-1992		
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	A5	wo	98/05635	. /	A1	CHIROSCIENCE LIMITED	02-12-1998	NOV 2 7 2002	
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	A8	wo	98/15294	/	A1	THE UNIVERSITY OF SHEFFIELD	04-16-1998		
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	A10	wo	99/15683	-	A1	OXFORD BIOMEDICA LIMITED	04-01-1999		
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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS									
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>'8</sup>						
90)	A14	BOWTELL et al., "Comparison of Expression in Hemopoietic Cells by Retroviral Vectors Carrying Two Genes," <u>Journal of Virology</u> , 62(7):2464-2473, American Society for Microbiology, July 1988							

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		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue nur publisher, city and/or country where published.				
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		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS
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